

REMARKS

I. STATUS OF THE CLAIMS

After entry of this amendment, claims 41, 43, 48, 51-52, 56, 75-77, 79-82, and 86-103 are pending in this application and are presented for examination. Claims 1-40, 42, 44-47, 49-50, 53-55, 57-74, 78, and 83-85 have been canceled without prejudice to future prosecution. Claims 48, 51-52, and 86 are allowed. Claims 43, 77, 79-80, 88-91, 95, 97, 99, and 100 have been amended. Claim 103 is newly added.

Claims 43, 79, 88, 90, 95, 97, and 99 have been amended for purposes of clarity to address the Examiner's rejection of these claims as allegedly being indefinite.

Claims 80, 91, and 100 have been amended in view of the amendments to claims 77, 89 and 97, respectively. Support for the amendments to claims 77, 89, and 97 is found, for example, on page 5, lines 1-16, and on page 8, lines 15-30 of the instant specification.

New claim 103 finds support, for example, on page 19, lines 10-12 of the instant specification.

As such, no new matter has been introduced. Reconsideration is respectfully requested.

II. ELECTION/RESTRICTIONS

Applicants acknowledge with appreciation the Examiner's indication that search and examination has been extended to SEQ ID NO:3, as well as combinations of SEQ ID NO:5 and SEQ ID NO:3. The Examiner has also indicated that new method claims 97-102 have been rejoined and examined with the product claims since both of the presently pending composition and method claims appear to embrace allowable subject matter.

III. SPECIFICATION

In response to the present objection, Applicants have amended the specification to include the heading "Brief Description of the Drawings" on page 23 before line 5. Accordingly, Applicants respectfully request that the Examiner withdraw the present objection.

IV. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claim 41, 43-44, 79, 87-88, 90, 94-95, and 97-102 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse.

In an earnest effort to expedite prosecution but without acquiescing on the merits of the rejection, Applicants have made the following amendments to clarify the subject matter of the claimed invention:

1. Claim 43 has been amended to clarify that the nucleic acid molecule is purified or isolated from genomic DNA.
2. Claim 44 has been canceled with prejudice, thereby rendering the present rejection moot with respect to this claim.
3. Claim 79 has been amended to clarify that the nucleic acid molecule comprises a sequence consisting of from 14 to 24 nucleotides.
4. Claim 88 has been amended to clarify that the nucleic acid molecule is a probe when it comprises a detectable label.
5. Claim 90 has been amended to clarify that each of the first and second nucleic acid molecules comprises a sequence consisting of from 14 to 24 nucleotides.
6. Claim 95 has been amended to clarify that each of the first and second nucleic acid molecules is a probe when it comprises a detectable label.
7. Claim 97 has been amended to clarify that step (c) comprises the active step of determining the presence of or predisposition to adult-type hypolactasia in a subject based upon the presence or absence of hybridization between the first or second nucleic acid molecule with the nucleic acid obtained from the subject.
8. Claim 99 has been amended to clarify that each of the first and second nucleic acid molecules comprises a sequence consisting of from 14 to 24 nucleotides.

As such, Applicants respectfully request that the Examiner withdraw the present rejection under 35 U.S.C. § 112, second paragraph.

V. REJECTION UNDER 35 U.S.C. § 101

The Examiner has rejected claims 56, 77, 79, 87-90, and 94-95 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. Applicants respectfully traverse.

In an earnest effort to expedite prosecution but without acquiescing on the merits of the rejection, Applicants have amended claims 77 and 89 (as well as claim 97) in accordance with the Examiner's suggestion to recite a "purified or isolated" nucleic acid molecule. Thus, Applicants respectfully request that the Examiner withdraw this rejection.

VI. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 56, 75, 77, 79-82, and 87-102 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Applicants respectfully traverse.

In the Office Action, the Examiner acknowledges that the instant specification is enabling for isolated nucleic acid molecules that hybridize under highly stringent conditions of the particular type specified at page 5, lines 12-15 of the instant specification (including both hybridization and wash conditions) to SEQ ID NO:3/5 (or the complement thereof), as well as compositions and methods including such nucleic acid molecules.

However, the Examiner alleges that the specification does not reasonably provide enablement for the breadth of the nucleic acid molecules as presently claimed. In particular, the Examiner contends that the instant claims are not directed to fragments of SEQ ID NOS:3 and/or 5 that include position 324, but instead embrace sequences of at least 14 nucleotides of SEQ ID NO:3/5 that may be flanked on either side by thousands of nucleotides of unrelated sequences.

In an earnest effort to expedite prosecution but without acquiescing on the merits of the rejection, Applicants have amended claims 77, 89, and 97 to recite that the nucleic acid molecule comprises a sequence that corresponds to a *fragment of SEQ ID NO:3/5* or a *fragment of the complementary sequence*. The sequence of the nucleic acid molecule consists of from *14 to 30* consecutive nucleotides of SEQ ID NO:3/5 which includes position 324 of SEQ ID NO:3/5 and hybridizes under *highly stringent conditions* to the complementary sequence, or consists of from *14 to 30* consecutive nucleotides of the complementary sequence to SEQ ID NO:3/5 which

includes position 324 of the complementary sequence and hybridizes under *highly stringent conditions* to SEQ ID NO:3/5.

Applicants assert that the instant specification clearly enables one of skill in the art to practice the full scope of the claims without undue experimentation. For instance, page 5 at lines 11-16 of the specification provides numerous examples of *highly stringent conditions*, including specific hybridization and washing conditions. Notably, page 5 at lines 5-11 of the instant specification discloses that appropriate stringent conditions for each sequence may be established on the basis of well-known parameters such as temperature, nucleic acid molecule composition, salt conditions, *etc.*, and also provides numerous examples of laboratory manuals describing nucleic acid hybridization strategies. In addition, page 8 at lines 15-18 and 28-30 of the instant specification describes *fragments of nucleic acid molecules such as SEQ ID NO:3/5* having at least 14 nucleotides such as 30 nucleotides (*i.e.*, from 14 to 30 consecutive nucleotides) and including nucleotide position -13910 of the LPH gene, *i.e.*, position 324 of SEQ ID NO:3/5. Applicants further note that Example 3 of the specification provides an example of a nucleic acid molecule (SEQ ID NO:10 on page 30) comprising a *fragment of SEQ ID NO:3* which consists of a sequence of from 14 to 30 consecutive nucleotides of SEQ ID NO:3 and includes position 324 of SEQ ID NO:3.

As such, Applicants submit that the specification provides ample guidance for one of skill in the art to practice the claimed methods without undue experimentation. In particular, the instant claims as amended are not directed to sequences that may be flanked on either side by thousands of nucleotides of unrelated sequences as alleged by the Examiner. Rather, Applicants assert that the nucleic acid molecules set forth in claims 77, 89, and 97 (and dependent claims) encompass *fragments of SEQ ID NO:3/5* or *fragments of the complementary sequence* which have a specifically defined length of from 14 to 30 consecutive nucleotides (and include position 324) and which hybridize under *highly stringent conditions*. Therefore, Applicants believe that one of skill in the art would be able to practice the full scope of the instant claims without undue experimentation.

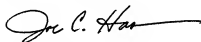
Accordingly, Applicants respectfully request that the Examiner withdraw the present rejection under 35 U.S.C. § 112, first paragraph.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



Joe C. Hao
Reg. No. 55,246

KILPATRICK TOWNSEND & STOCKTON LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 925-472-5000
Fax: 415-576-0300
JCH
63794980 v1